

## **REMARKS**

### **I. Status of the Claims**

Claims 1, 3-38, 43-45, 53, 54, 65, 66, 70, 73, 74, 76-80 and 85-87 are pending. Claims 1 and 3-36 have been withdrawn. None of the claims have been amended.

### **II. Rejections under 35 U.S.C. § 102(b)**

Independent Claim 37 and dependent Claims 38, 43-45, 54, 65, 66, 70, 73 and 74 were rejected under 35 U.S.C. § 102(b) for being allegedly anticipated by Martin, *et al.* "In-Channel Electrochemical Detection for Microchip Capillary Electrophoresis Using an Electrically Isolated Potentiostat" Anal. Chem. Vol. 74, no. 5, 2002, pp. 1136-1143. Applicant respectfully traverses this rejection.

It is axiomatic that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or [is] inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of Cal.*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The requirement that the prior art elements themselves be arranged as in the claim means that claims cannot be "treated ... as mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning." (*See Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984); *see also Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 88 USPQ2d 1751 (Fed. Cir. 2008) ("[U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. §102.").)

Martin discloses a method of electrochemical detection using a device comprising two layers of poly(dimethylsiloxane) (PDMS), wherein one layer contains a separation channel and a second layer contains an electrode channel. Martin, p. 1138. The device is constructed by manually aligning the two layers through the use of a light microscope and calibrated reticule. *Id.*

In contrast, claim 37 recites a method of performing electrophoresis comprising attaching a first conductive element and a second conductive element to a microchip having at least one microfluid thereon, wherein said microchip comprises at least one main separation channel formed in a channel forming medium, said main channel containing at least one microfluid; at least one detecting channel containing a first conductive wire, fiber or paste for performing electrochemical detection, said detecting channel being formed in said channel forming medium and adjoining said main channel; and at least one reservoir containing said second conductive element to provide a reference to said first conductive element, said reservoir being formed in said channel forming medium and containing waste; and applying continuous or pulsed amperometric detection to said microchip using said conductive elements, wherein specimens within said microfluid migrate toward said first conductive wire and, wherein electrical contact with said first conductive wire, fiber or paste generate a measurable signal.

Unlike Martin, the presently claimed microchip comprises a separation channel and a detection channel formed in the same channel forming medium. Martin does not disclose a method of performing electrophoresis comprising a device wherein the separation channel and the detection channel are formed in the same channel forming medium. Rather, Martin discloses forming a separation channel in one layer and a forming a detection channel in a second layer, wherein the two layers are then aligned to achieve the desired position of the detection channel in relation to the separation channel.

Accordingly, Martin does not disclose each and every feature of claim 37, nor does Martin disclose all of the features arranged or combined in the same way as recited in claim 37. Claims 38, 43-45, 54, 65, 66, 70, 73 and 74 depend directly or indirectly from claim 37, and thus, incorporate all of the features of claim 37. Therefore, Applicants respectfully submit that Martin does not anticipate the presently claimed invention under 35 U.S.C. § 102(b), and the rejection of claims 37, 38, 43-45, 54, 65, 66, 70, 73 and 74 should be reconsidered and withdrawn.

### **III. Rejections under 35 U.S.C. § 103(a)**

Claims 53 and 85-87 were rejected under 35 U.S.C. 103(a) as allegedly obvious in view of Martin. Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, the Patent Office must show, *inter alia*, that the cited references teach or suggest all the claim limitations. Manual of Patent Examination and Procedure (M.P.E.P.) § 2143.03; *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974). Additionally, the Office must consider, "(1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success." *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991); *see also Dystar Textilfarben GmbH & Co. Deutschland Kg v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006). The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. § 103 should be made explicit. *KSR International v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007), quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Furthermore, it is improper to merely identify elements in various cited references, because doing so "would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention." *See In re Rouffet*, 149 F.3d 1350, 1357-58 (Fed. Cir. 1998).

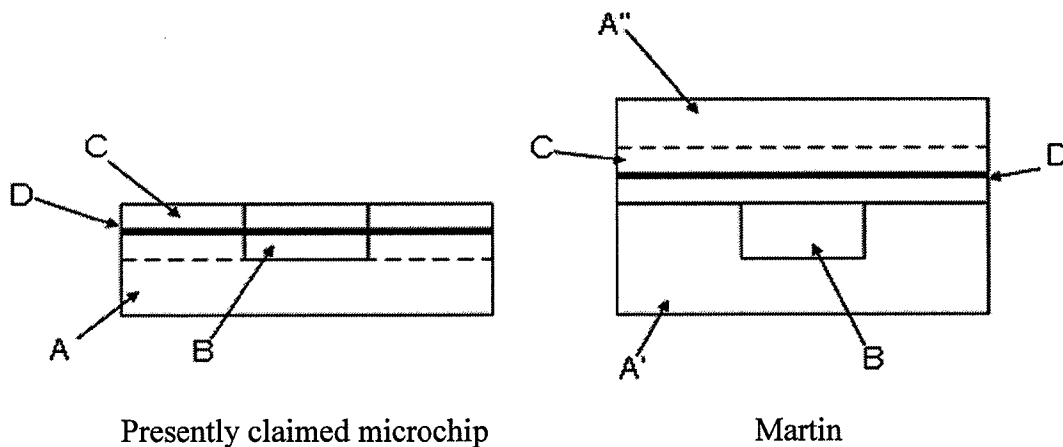
Claims 53 and 85-87 depend either directly or indirectly from claim 37, and therefore incorporate each and every feature of claim 37. As discussed above, Martin does not disclose each and every feature of claim 37, nor does Martin disclose all of the features arranged or combined in the same way as recited in claim 37.

Rather, Martin discloses a device comprising two layers, wherein the layer containing the detection channel is manually aligned with the layer containing the separation channel using a light microscope and a reticule. Martin, p. 1138. This tedious and difficult alignment step results in variations in the effective separation length of the separation channel ( $L_{\text{eff}}$ ), which negatively impact the separation efficiency of the device. For example, variations in  $L_{\text{eff}}$  contribute to band dispersion through either decreasing the number of theoretical plates of the separation channel and/or increasing the total plate height in the separation channel. In fact, Martin acknowledges these impacts in stating that "all of the experimental parameters except

electrode alignment were kept constant ... and any change in [plate height] should reflect only the contribution of the [plate height originating from the electrochemical detector]." *Id.* p. 1141. Thus, the separation efficiency of the devices disclosed in Martin is severely limited by the precision with which the alignment step is carried out.

In contrast, the presently claimed invention recites a microchip comprising a separation channel and a detection channel formed in the same channel forming medium. Accordingly, any variation  $L_{eff}$  is reduced or eliminated because the detection channel is in a fixed orientation compared to the separation channel. Thus, the presently claimed invention has a much greater separation efficiency compared to the devices disclosed in Martin. Additionally, the elimination of an alignment step makes the presently claimed invention more suitable for reproducibility and mass-production.

Furthermore, the presently claimed device achieves a greater level of detection compared to the devices disclosed in Martin. The illustration below is a cross-sectional view of the presently claimed microchip compared to the device disclosed in Martin.



As can be seen from the figure, the presently claimed microchip has a separation channel (B) and a detection channel (C) formed in a single channel forming medium (A). The electrode (D) is placed within the detection channel (C), and thus, has a greater exposed surface area in the separation channel (B). In contrast, Martin discloses forming the separation channel (B) in a first medium (A') and the detection channel (C) is formed in a second medium (A''). Thus, the electrode (D) does not lie within the plane of the separation channel (B).

The electrode of the microchip in the presently claimed method has a larger exposed surface area when it is placed directly in the plane of the separation channel, and thus greater

detection capabilities. In contrast, the "in-channel" embodiment disclosed in Martin is misleading, because the detection electrode in Martin is does not actually lie "in" the plane of the separation channel.

Accordingly, Martin does not disclose each and every feature of the presently claimed invention, and the Office has not provided some articulated reasoning with some rational underpinning to support its legal conclusion of obviousness. Therefore, for at least these reasons, Applicants respectfully submit that rejection of claims 53 and 85-87 under 35 U.S.C. § 103(a) in view of Martin be reconsidered and withdrawn.

#### IV. Conclusion

Applicants submit that the claims as presented herein are now in further condition for allowance or appeal. The Examiner is invited to telephone the undersigned representative at 202-625-3676 should the Examiner have any questions or comments that would expedite issuance of the present application.

The Commissioner is hereby authorized to charge Attorney's Deposit Account Number 50-1710 for any fees which are due and owing.

Respectfully submitted,



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